4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0352]

Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use; Reopening of Comment Period

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of intent; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for public scoping on the environmental impact statement (EIS) described in the notice entitled "Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use" that appeared in the *Federal Register* of May 13, 2021. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for public scoping on the EIS identified in the notice published May 13, 2021 (86 FR 26224). To ensure the Agency considers your comments before it begins work on the draft EIS, submit either electronic or written comments on the scoping process discussed in the notice by July 14, 2021. If a virtual public scoping meeting is scheduled, FDA will announce the date and time via the weblink "Environmental Impact Statement (EIS) for Certain Sunscreen Drug Products" on the Agency's web page "Guidance, Compliance, & Regulatory Information," available at https://www.fda.gov/drugs/guidance-compliance-regulatory-information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 14, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 14, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked

or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0352 for "Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products

for Over-the-Counter Use." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Trang Q. Tran, Center for Drug Evaluation

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4139, Silver Spring, MD 20993; 240-402-7945.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of May 13, 2021 (86 FR 26224), FDA published a notice entitled "Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use," which announced the initiation of a public scoping period that would end on June 14, 2021, and noted that comments on scoping would need to be submitted prior to the close of this period. In response to a request submitted to the docket, FDA is reopening the comment period for public scoping on the EIS for an additional 30 days, until July 14, 2021. The Agency believes that a 30-day extension will allow adequate time for interested persons to submit comments without significantly delaying publication of the draft EIS.

II. Electronic Access

Persons with access to the internet may obtain the notice of intent through the Agency's weblink "Environmental Impact Statement (EIS) for Certain Sunscreen Drug Products," available at https://www.fda.gov/drugs/guidance-compliance-regulatory-information or by searching for the above docket number at https://www.regulations.gov.

Dated: June 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-13568 Filed: 6/24/2021 8:45 am; Publication Date: 6/25/2021]